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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,270	01/26/2002	George E. Fox	010AUS	3019
26830 7590 04/30/2008 RICHARD COALE WILLSON JR 3205 HARVEST MOON DR STE 200 PALM HARBOR, FL 34683-2127				
EXAMINER SIMS, JASON M				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/057,270

Applicant(s)

FOX ET AL.

Examiner

JASON M. SIMS

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-10, 21, 23, 24 and 26-39 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-10, 21, 23, 24, 26-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 4 and 26-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election without traverse of Claims 4-10, 21, 23-24, and 26-32 and the Species of claim 30 in the reply filed on 12/14/2007 is acknowledged.

Applicant's cancellation of claims 1-3, 11-18, 20, and 22 in the response filed 12/14/2007 is acknowledged.

Claims 31 and 33-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/14/2007.

Applicant's arguments, filed 8/32/2007, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 8/32/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 4-10, 21, 23-24, 26-30, and 32 are the current claims hereby under examination.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 comprises in appropriate claim formatting. Each of steps A-E should end in the appropriate punctuation, a semicolon. For example, claim 4, step A inappropriately ends with a period and step B does not end with any punctuation,

Art Unit: 1631

wherein step E ends with an appropriate semicolon. Appropriate correction is required.

Claims 26-39 are objected to for having inappropriate claim numberings. Claim number 25 is missing from the claim numbers. Therefore, claims 26-39 should appropriately be renumbered as claims 25-38.

Claim Rejections - 35 USC § 112

Response to Arguments:

Applicant's arguments, filed 8/32/2007, with respect to the rejection under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendment. Therefore the rejection has been withdrawn.

The following rejections have been necessitated by amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10, 21, 23-24, 26-30, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, step A, comprises the term "substantially," which is vague and indefinite and is not defined by the claim. It is unclear as to what constitutes the term "substantially" and/or metes and bounds of said term. Therefore, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Clarification via clearer claim wording is required.

Claim 4, step A, comprises the wording "in a database of sequences of the nucleic acid," which has been deemed as vague and indefinite. It is unclear as to what exactly said wording refers. It appears that the organisms or viruses in a database all comprise a particular nucleic acid along with other sequences in the database for said organisms and viruses. Clarification via clearer claim wording is required.

Claim 4, step B, comprises the wording "Identifying the extent to which each particular oligonucleotide or sequence of length N is characteristic of each node," which has been deemed as vague and indefinite. It is unclear as to how each oligonucleotide will be characteristic of each node in the bifurcating node phylogenetic tree.

Claim 4, step B, comprises the wording "each particular oligonucleotide or sequence of length N," which has been deemed as vague and indefinite. It is unclear as to which sequences or oligonucleotides are being referenced. For instance, it is unclear as to the exact differences between the sequences in the database and the nucleic acid and therefore it remains vague and indefinite as to which sequence is being reference in the instant vague and indefinite wording. Clarification via clearer claim wording is required.

Claim 4, steps B and C are deemed as vague and indefinite. It is unclear as to how identifying how each particular oligonucleotide is characteristic of each node plays a role in creating or deriving a signature database of signature sequences. If each of steps A-F are independent of each other, then it is equally vague and indefinite as to how the signature database is created or how

"signature probes" are derived from said signature database. Clarification via clearer claim wording is required.

Claim 4, step C, comprises the wording "Deriving a plurality of nucleic acid signature probes from a signature database of signature sequences," which has been deemed as vague and indefinite. It is unclear as to what exactly a "signature database" comprises. Furthermore, it is unclear as to what the wording "signature probes" or "signature sequences" mean. For instance, it appears that "signature sequences" may be consensus sequences or conserved sequences across different organisms. In addition, because it is unclear as to what the wording "signature sequences" or "signature probes" refers, it further unclear as to how these probes are used to identify twice the number organisms as number of probes used. Clarification via clearer claim wording is required.

Claim 4, step C, comprises the wording "the nucleic acid sequence," which has been deemed as vague and indefinite. It is unclear as to which nucleic acid sequence of the organism or virus is being referenced. Clarification via clearer claim wording is required.

Claim 4, step C, comprises the wording "the number of organisms or viruses whose genetic affinity might be determined is at least twice the number of probes used," which has been deemed as vague and indefinite. It is unclear as to what exactly the word "might" refers. It is unclear as to whether the signature probes are **actually capable** of identifying twice the number of **different** organisms or viruses as the number of probes used or if the wording might be referring to twice the number of the same organisms. It is unclear as to

Art Unit: 1631

what determines the **potential** of the probes for identifying the genetic affinity of twice the number of organisms or viruses in a sample than the number of probes used in cases wherein twice the number of organisms or viruses are not identified, which is what the word "might" infers. Clarification via clearer claim wording is required.

Claim 4, step F, comprises the vague and indefinite wording "which nodes in the bifurcating node phylogenetic tree of genetic relationship produced detectable signal." It is unclear as to how the nodes produce detectable signals. It remains further unclear as to how the detectable signals result in a determination of identifying the closest genetic relatives of the organism or virus in the test sample. Clarification via clearer claim wording is required.

Claim 10, step A and step B, comprises the wording "substantially homologous RNA or DNA" and "substantially every oligoribonucleotide," which has been deemed as vague and indefinite. It is unclear as to what constitutes the term "substantially" and/or metes and bounds of said term. Therefore, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Clarification via clearer claim wording is required.

Claims 23 and 30, the equation variables NGM2 and "N GM" have been deemed as vague and indefinite. It is unclear as to whether NGM2 is defined as the same as NGM or is a separate variable without properly being defined. Furthermore, it is unclear as to whether "N GM" are two separate variables without proper definitions or the same variable as "NGM." Clarification via clearer claim wording is required.

Claim 26 is being rejected because it comprises a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim), which is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 26 recites the broad recitation wherein 15 sequences are used to determine the genetic affinity of at least 18 organisms, and the claim also recites the number of organisms or viruses whose genetic affinity might be determined is at least twice the number of probes, which is the narrower statement of the range/limitation.

Claim 27 has been deemed as vague and indefinite. It is unclear as to how the failure to detect a particular sequence results in increased confidence with which the genetic affinity of an organism or virus is determined. Clarification via clearer claim wording is required.

Claim 28 is being rejected because it comprises a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim), which is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the broad recitation wherein more than one oligonucleotide or sequence is detected, and the claim also recites the number of organisms or viruses whose genetic affinity might be determined is at least twice the number of probes, which is the narrower statement of the range/limitation.

Claims 5-9, 21, 24, 29, and 32 are rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 103

Response to Arguments:

Applicant's arguments, filed 8/23/2007, with respect to the rejection of claims under 35 USC 103 have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

The following rejection has been necessitated by amendment:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Ebersole et al. (US P/N 6,797,817).

The claims are directed to a method for determining the genetic affinity of organisms or viruses in a test sample containing a nucleic acid comprising the steps of:

A) Obtaining or developing a bifurcating node phylogenetic tree that substantially reflects the genetic relationship between the organisms or viruses included in a database of sequences of the nucleic acid.

B) Identifying the extent to which each particular oligonucleotide or sequence of length N is characteristic of each node in the bifurcating node phylogenetic tree of genetic relationship.

C) Deriving a plurality of nucleic acid signature probes from a signature-database of signature sequences that are complementary to a portion of the nucleic acid sequence of the organism or virus such that the number of organisms or viruses whose genetic affinity might be determined is at least twice the number of probes used.

D) Hybridizing the signature probes to the nucleic acid obtained from the test sample under conditions where a detectable signal will be produced by signature probes that hybridize to the nucleic acid of the organism or virus.

E) Identifying signature probes which produce detectable signal.

F) Determining which nodes in the bifurcating node phylogenetic tree of genetic relationship produced detectable signal to identify the closest genetic relatives of the organism or virus in the test sample.

Ebersole et al. teaches at Col. 9, lines 35-45 that a phylogenetic Tree of Life was obtained and used for extracting sequences that represented the major microorganism domains, Bacteria and Archeae, which could be used as signature sequences for obtaining signature probes for testing for the presence of dechlorinating bacteria, which reads on method steps A-C. Furthermore, Ebersole et al. teaches at col. 4, lines 55-67 and col. 5, lines 1-4, that sequence profiles, from which signature probes are derived, may be used to identify and subtype bacteria with similar metabolic pathways. Therefore, a signature probe may be used to identify a dechlorinated bacteria and/or bacteria with similar metabolic pathways, such as subspecies of dechlorinates, which further reads on step C) Deriving a plurality of nucleic acid signature probes from a signature-

Art Unit: 1631

database of signature sequences that are complementary to a portion of the nucleic acid sequence of the organism or virus such that the number of organisms or viruses whose genetic affinity might be determined is at least twice the number of probes used. Ebersole et al. further teaches at col. 4, lines 55-67 and col. 5, lines 1-4 that the use of particular sequences may be used to identify dechlorinators as well as for genetic sub-typing of species, which further reads on method step B) Identifying the extent to which each particular oligonucleotide or sequence of length N is characteristic of each node in the bifurcating node phylogenetic tree of genetic relationship. Ebersole et al. further teaches at col. 2, lines 51-65, the use of signature probes in hybridizing to identifying sequences such that a signal is detectable, which reads on step D) Hybridizing the signature probes to the nucleic acid obtained from the test sample under conditions where a detectable signal will be produced by signature probes that hybridize to the nucleic acid of the organism or virus. Ebersole et al. at col. 5, lines 34-39, col. 6, lines 31-34, col. 6, lines 58-67, and col. 7, lines 1-9 teaches using signature sequences for generating probes and defines the use of probes and hybridization as such that is consistent in the art, which produce detectable signals, which reads on step E) Identifying signature probes which produce detectable signal. Ebersole et al. teaches at col. 8, lines 38-40 that the sequences are useful for the identification of new dechlorinating bacteria, as well as for sub-typing strains of *Dehalococcoides ethenogenes*. Furthermore, Ebersole et al. teaches at col. 9, lines 19-40 that sequences used for obtaining probes and closest or nearest organisms to these sequences were determined,

which all read on step E) Determining which nodes in the bifurcating node phylogenetic tree of genetic relationship produced detectable signal to identify the closest genetic relatives of the organism or virus in the test sample.

Ebersole et al. teaches claim 5 at col. 2, lines 50-59 wherein rDNA are used for obtaining probes, which reads the use of DNA for comprising signature probes.

Ebersole et al. teaches claim 6 at col. 6, lines 58-67 wherein hybridization is taught with that which is consistent in the art wherein a hybridization step is done in solution, which reads on claim 6.

Ebersole et al. teaches claim 7 at col. 13, lines 25-30 wherein it is taught that probes which generate a detectable signal are used, which inherently reads on a probe wherein the detection step utilizes radioactive labels, chemiluminescence, and/or fluorescence.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

Art Unit: 1631

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin, Ph.D./

Primary Examiner, Art Unit 1631

